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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,172	08/22/2000	Meir Edelman	EDELMAN-1	1629
1444	7590	11/18/2003	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			MEHTA, ASHWIN D	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 11/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/529,172	EDELMAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ashwin Mehta	1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 12-36, 54-58, 62, 63 and 65-67 is/are pending in the application.
- 4a) Of the above claim(s) 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 12-18, 20-30, 32, 34-36, 54-58, 62, 63 and 65-67 is/are rejected.
- 7) ☒ Claim(s) 31 and 33 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objection to the specification for failing to comply with 37 CFR 1.821-1.825 is withdrawn, in light of the submission of paper and computer-readable forms of the sequence listing, and insertion of sequence identifiers in the relevant locations of the specification.
3. The objection of claims 2-8, 13-18, 21, 22, 24, 26-35, 56, 57, 62, and 63 for a minor informality is withdrawn.
4. The rejection of claims 9-11 under 35 U.S.C. 101 is withdrawn, in light of the cancellation of the claims.
5. The rejection of claim 11 under 35 U.S.C. 102(b)/103(a) is withdrawn, in light of the cancellation of the claim.

### ***Election/Restrictions***

6. Applicants traverse the restriction of claim 19 in the paper filed July 15, 2003. Applicant argues that dependent claims 21 and 22 do not require the plant to be a Lemnaceae plant, and that claims 19-21 share the same inventive concept (response, paragraph bridging pages 17-18).

However, claims 19 and 20 do not share the same inventive concept. The transformation of non-Lemnaceae plants, encompassed by claim 19, is not shared with claim 20. Further, in the response to the restriction requirement, submitted February 26, 2002, Applicants argued that claim 20 is directed to a method for genetic transformation of Lemnaceae plants, that claim 1 is directed to genetically stable, transformed Lemnaceae plants, that claim 23 is directed to a method for genetic transformation of Lemnaceae plants, and that claims 20-24, 62, and 63 have unity of invention with the claims of Group I. The claims of Group I are drawn to genetically stable, transformed Lemnaceae plants and methods for the stable genetic transformation of Lemnaceae plants comprising incubation with Agrobacterium cells. The Examiner agreed to rejoin claims 20-24, 62, and 63 with the claims of Group I, because Applicants explained how they share the same inventive concept of being drawn to a method for the stable genetic transformation of Lemnaceae plants comprising incubation with Agrobacterium cells. Furthermore, the Office action mailed January 15, 2003, indicated that the elected claims should be amended so that they no longer encompass non-elected inventions. The restriction requirement is still deemed proper and remains FINAL.

Applicants are reminded that a complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

***Priority***

7. The change in the manner in which the benefit of PCT/IL97/00328 is claimed is acknowledged. In the paper submitted July 15, 2003, Applicant designated the PCT application,

PCT/IL98/000487, of which the present application is the national phase under 35 U.S.C. 371, as a continuation-in-part of PCT/IL97/000328.

As the oath/declaration claims foreign priority to PCT/IL97/000328 under 35 U.S.C. 119, Applicants are asked to submit a new oath/declaration that reflects the change in priority, so that it is consistent with the application data sheet submitted on July 15, 2003.

### ***Claim Objections***

8. Claims 2, 31, and 33 are objected to for the following reasons:

Claim 2 is objected to because of the following informalities: in line 3, "Wolffica" is misspelled. While the claim amendments submitted on July 15, 2003 do not indicate that this term was amended, its spelling as it appears in the claim is different from the way it appears in the originally submitted claim.

Claims 31 and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Claim Rejections - 35 USC § 112***

9. Claims 1-8, 20-24, 36, 54-57, 62, and 63 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed January 15, 2003. Applicants traverse the rejection in the paper filed July 15,

2003. Applicants' arguments were fully considered but were not found persuasive for the rejections discussed below.

Claim 1, for the recitation, "progeny thereof": Applicants direct attention to the definition for "stable transformation" on page 3 of the specification, and argue that the term denotes such a genetic transformation that is heritable to future generations. Applicants argue that by definition, the foreign DNA of the plant of claim 1 is heritable to progeny (response, page 22, 1<sup>st</sup> full paragraph). However, the rejection is not questioning whether any foreign DNA is heritable, but rather whether the progeny has actually inherited it. If the transformed plant has only a single copy of a heritable foreign DNA, then there is a 50% chance that a progeny plant will not inherit it. Yet, the claim does not discriminate between progeny that have inherited the foreign DNA, and those that have not.

Claims 20-23, 36, 62, and 63, for being dependent upon a non-elected claim: Applicants request that if claim 19 is not reinserted, that the rejection be held in abeyance until a final decision has been reached (response, paragraph bridging pages 23-24 and page 25, 7<sup>th</sup> full paragraph). Applicants' argument is acknowledged. The rejection will be maintained until such final decision has been reached. Claims 21 and 22 will continue to be examined until such time as if the plant of claim 19 is a Lemnaceae plant.

10. Claims 66 and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 66: the recitation, “a genetically stable Lemnaceae plant” in line 1 renders the claim indefinite. The term, “genetically stable”, does not clearly indicate if the plant is stably transformed. It is suggested that “genetically stable” be replaced with --stably transformed--.

In claim 67: the recitation, “stably transferred” in line 3 renders the claim indefinite. It is not clear what is meant by the recitation. It is suggested that “transferred” be replaced with --transgenic--.

11. Claims 1-8 remain and claims 54-57 and 67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed January 15, 2003. Applicants traverse the rejection in the paper filed July 15, 2003. Applicants' arguments were fully considered but were not found persuasive.

Applicants argue that, when claiming a product, it is not necessary to recite the method of making it, and that adding such a process limitation would not distinguish the claim from prior art made in another way. Applicants argue that product-by-process claims are never required if the product can be adequately described by characterization as opposed to a method of making it (response, paragraph bridging pages 27-28). However, every transgenic Lemnaceae plant described in the specification was produced by an Agrobacterium-mediated method. Such transgenic plants would be different from transgenic plants produced by other methods because of the presence of the Agrobacterium T-DNA. The method of making the claimed plants

described in the specification does distinguish it from any other method of making it. Applicants ask the rhetorical question that if an application claimed a novel compound and the specification indicates that there is only one way of making that compound, would the examiner require that the sole process of making the compound to be inserted into the claim? Applicants contend that the examiner would not make this requirement (response, paragraph bridging pages 27-28).

However, this example is not analogous to the instant application. Other methods to transform duckweed have been described. U. S. Patent No. 6,040,498 describes a particle bombardment-mediated method to transform duckweed tissues and regenerate transgenic plants (col. 31, line 55 to col. 33, line 11). However, the instant application only describes *Agrobacterium*-mediated methods, and admits that the Applicants could not transform duckweed by microparticle bombardment. The instant claims, however, still encompass transgenic plants produced by undescribed methods. Claims 54-57 and 67 are included in the rejection as they are drawn to methods involving starting materials that are not described, as discussed above. See 64 Fed. Reg. 71427, 71428 (1999), comment No. 4.

12. Claim 3 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the Office action mailed January 15, 2003.

Applicants traverse the rejection in the paper filed July 15, 2003. Applicants' arguments were fully considered but were not found persuasive.



Applicants admit that they did not invent *Spirodela punctata* strain 8717 and that they are still investigating the public availability of this strain. Applicants state that if they determine that this strain is not publicly available, then a depository statement will be made (response, page 29, 1<sup>st</sup> full paragraph). Applicants' intent and continuing investigation is acknowledged. The rejection is maintained.

13. Claims 1-8, 54-57, and 67 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for genetically stable, transformed Lemnaceae plants produced via *Agrobacterium*, and a method of production of a product of interest, comprising growing a stably transgenic Lemnaceae plant produced via *Agrobacterium*, does not reasonably provide enablement for genetically stable, transformed Lemnaceae plants produced by any other method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn towards any genetically stable, transformed Lemnaceae plant and progeny thereof; a method of production of a product of interest, comprising growing said Lemnaceae plant.

The specification describes a method for the stable transformation of *Lemna* and *Spirodela* plants by microinjection with *Agrobacterium*. The bacterial cells were microinjected into meristematic zones (pages 13-17; 20-22). The specification describes the *Agrobacterium*-mediated transformation of *Lemna* and *Spirodela* particles and regeneration of plants therefrom. The particles were produced by blending, ranges in size from 350-750  $\mu\text{m}$ , and contained

meristematic zones. Particles that were 150-350  $\mu\text{m}$  in size gave drastically reduced numbers of actively growing plants. Transgenic plants were recovered that contained a kanamycin resistance gene (pages 22-25). The specification also indicates that 5 different *Agrobacterium* strains were used in the transformation procedure, and that strains EHA105, EHA101, and GVE3103 only transformed meristematic tissue, whereas strains LBA4404 and C58 were restricted to transforming wounded areas of the mother frond (pages 25-26). The specification also indicates that vacuum infiltration of the *Agrobacterium* increased the transformation efficiency (page 27). The specification also indicates that transformation efficiencies were increased by removing the daughter fronds and exposing the mother frond meristematic zones, and co-cultivating *Agrobacterium* in a *Spirodela* extract prior to transformation (pages 28-29). Lemnaceae plants were also transformed with genes conferring resistance to the herbicide BASTA (pages 32-33).

However, the specification does not teach genetically stable, transformed Lemnaceae plants produced by any other method. The specification teaches disadvantages of plant transformation via particle bombardment (page 2, lines 12-21), thereby discouraging one skilled in the art from producing the claimed plants by this method. The specification also admits that the inventors of the instant invention attempted and failed to produce the claimed plants by particle bombardment (page 3, lines 12-15). The specification also teaches that various attempts in the past to stably transform Lemnaceae plants have been unsuccessful (page 3, lines 6-9). Given that the specification teaches that methods to stably transform Lemnaceae plants were not known in the prior art, undue experimentation would be required by one skilled in the art to make the claimed stably transformed Lemnaceae plants by any method other than those taught in

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the specification, which involve the use of *Agrobacterium*, and transfer of DNA of interest into duckweed cells via T-DNA. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

14. Claims 1, 2, 4-8, 12-16, 18, 20, 25, 26, 28, 36, and 54-57 remain and claims 65-67 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Stomp et al. (U.S. Patent No. 6,040,498), in light of Stachel et al. (Nature, 1985, Vol. 318, pages 624-629), for the reasons of record stated in the Office action mailed January 15, 2003. Applicants traverse the rejection in the paper filed July 15, 2003.

Applicants request an interference with the U.S. Patent No. 6,040,498, and submit statements under 37 CFR 1.607 and 1.608(a) (response, page 30, 1<sup>st</sup> full paragraph). The 608(a) statement states that there is a basis upon which the Applicants are entitled to a judgment relative to the patentee. However, the interference will not be considered until all other rejections have been overcome.

15. Claim 3 remains rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Stomp et al. (U.S. Patent No. 6,040,498), for the reasons

of record stated in the Office action mailed January 15, 2003. Applicants traverse the rejection in the paper filed July 15, 2003.

Applicants also address this rejection with the request for interference (response, page 30, 3<sup>rd</sup> full paragraph). The rejection is maintained, for the reasons discussed above.

16. Claims 1, 2, 4-8, 12-18, 20-30, 32, 34-36, 54-58, 62, and 63 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Stomp et al. (U.S. Patent No. 6,040,498) in view of Stachel et al. (Nature, 1985, Vol. 318, pages 624-629), Vernade et al. (J. Bacteriol., 1988, Vol. 170, pages 5822-5829), Bechtold et al. (C.R. Acad. Sci. Paris, Sciences de la vie /Life Sciences, 1993, Vol. 316, pages 1194-1199), and Grimsley, N. (Agroinfection, In Methods in Molecular Biology, Vol. 44: Agrobacterium Protocols, 1995, K.M.A. Gartland and M.R. Davey, Eds., Humana Press Inc., Totowa, N.J.) ), for the reasons of record stated in the Office action mailed January 15, 2003. Applicants traverse the rejection in the paper filed July 15, 2003.

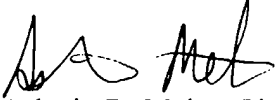
Applicants argue that if the Stomp patent is not available as a reference, the rejection must fall. Applicants state that they invented the invention prior to Stomp, and that this will be established in the interference proceeding (response, page 31, 1<sup>st</sup> full paragraph). The rejection is maintained for the reasons discussed above.

17. Claims 31 and 33 are objected to, claim 19 is withdrawn, and claims 1-8, 12-18, 20-30, 32, 34-36, 54-58, 62, 63, and 65-67 are rejected.

***Contact Information***

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

November 13, 2003

  
Ashwin D. Mehta, Ph.D.  
Primary Examiner  
Art Unit 1638